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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/797,344 | 03/10/2004 | Bill H. McAnalley | 23100.64 | 4291 |

27683 7590 04/08/2005

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| EXAMINER | |
|---|---|
| FLOOD, MICHELE C | |
| **ART UNIT** | **PAPER NUMBER** |
| 1654 | |

DATE MAILED: 04/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/797,344 | MCANALLEY ET AL. | |
| | Examiner | Art Unit | |
| | Michele Flood | 1654 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *21 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *1,2 and 9-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election of Group III, Claims 3-8, in the reply filed on January 21, 2005 is acknowledged. Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

**Claims 3-8 are under examination.**

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the limitation "the predigestion" in line 1. There is unclear antecedent basis for this limitation in the claim.

Claim 8 recites the limitation "The method of claim 5, wherein the biological digestion" in line 1. There is unclear antecedent basis for this limitation in the claim.

### *Claim Objections*

Claim 8 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is

required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. It appears that Claim 8 should depend from Claim 4. Appropriated correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Yamada et al. (NN1).

Applicant claims a method for producing correctly structured and properly functioning glycoproteins and/or glycolipids in a human comprising administering to a subject a dietary supplement comprising a nutritionally effective amount of at least one saccharide, in monomeric, oligomeric or polymeric form selected from the group consisting of galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine, xylose, arabinose, glucuronic acid, galacturonic acid, iduronic acid, arabinogalactan, acetylated mannose, glucosamine and galactosamine.

Yamada teaches a dietary supplement comprising a polysaccharide containing arabinose, galactose, glucose, rhamnose, galacturonic acid and glucuronic acid as the constituent saccharides. Yamada teaches the administration of the dietary supplement

comprising the polysaccharide to humans improves hematopoietic function and serves as a radioprotective agent for treating or reducing the risk of radiation injury. Yamada does not expressly teach the method of administering the dietary supplement as a method for producing correctly structured and properly functioning glycoproteins and/or glycolipids in a human. However, the method taught by Yamada comprises the administration of the same ingredients instantly taught by Applicant and provides the beneficial functional effect for improving hematopoietic function and treating or reducing the risk of radiation injury, which is indicative of improved cellular function in a human; and, thereby an indicator for the production of correctly structured and properly functioning glycoproteins and/or glycolipids, as instantly disclosed by Applicant in the present specification at [0062] and Table 4 in Column 11. Therefore, the claimed beneficial functional effect is inherent to the method of administering the dietary supplement to humans taught by Yamada.

The reference anticipates the claimed subject matter.

Claims 3-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Uchida (N).

Applicant's claimed invention of Claim 3 was set forth above. Applicant further claims the method of claim 3, wherein prior to administration, the oligomeric or polymeric forms of the saccharides are predigested into a mixture of mono and oligosaccharides. Applicant further claims the method of claim 4, wherein the predigestion is conducted by a digestion technique selected from physical digestion,

chemical digestion and biological digestion. Applicant further claims the method of claim 5, wherein the physical digestion is conducted by shearing or ultrasound treatment.

Uchida teaches a method for treating chronic fatigue syndrome comprising administering an effective amount of a polysaccharide having a beta -1, 3-glucoside bond in the main chain, also may having a 1,2-, 1,4- or 1,6-glucosed bond in a part an/or branched part of the chain, and wherein the polysaccharides may be a homopolysaccharide comprising the same monosaccharides, a heteropolysaccharide comprising various different saccharides or a complex polysaccharide. Examples of polysaccharides used in the method of treatment taught by Uchida include sizofiran, lentinan, pachyman, pachmaran produced by chemically modifying pachyman, paramylon, leucosin, xylan and dulxylan, curdlan, succinoglucan, sclerotan, scleroglucan, xanthan gum, laminaran, and pendulan. *See* page 3, Column 2, line 29 to Column 4, line 6. On page 3, Column 2, lines 7-21, Uchida teaches physical digestion of sizofiran by ultra-sonic treatment and high-shear treatment before administration of the agent. Uchida does not expressly teach the method of administering the dietary supplement as a method for producing correctly structured and properly functioning glycoproteins and/or glycolipids in a human. However, the method taught by Uchida comprises the administration of the same ingredients instantly taught by Applicant and provides the beneficial functional effect for treating chronic fatigue syndrome and associated disease conditions thereof (*e.g.,* fatigue, headaches, insomnia, depression, energy level, *etc.*) in a human patient, which is one of the same disease conditions

treatable by the method for the production of correctly structured and properly functioning glycoproteins and/or glycolipids, as instantly disclosed by Applicant in the present specification at [0056]. Therefore, the claimed beneficial functional effect is inherent to the method of administering the dietary supplement to humans taught by Uchida.

The reference anticipates the claimed subject matter.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 3 is rejected under 35 U.S.C. 103(a) as being obvious over Murray et al. (AQ or V, Robert K. Murray et al., Harper's Biochemistry, Appleton & Lange, 1996, pages 648-649.).

Applicant claims a method for producing correctly structured and properly functioning glycoproteins and/or glycolipids in a human comprising administering to a subject a dietary supplement comprising a nutritionally effective amount of at least one saccharide, in monomeric, oligomeric or polymeric form selected from the group consisting of galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine, xylose, arabinose, glucuronic acid,

galacturonic acid, iduronic acid, arabinogalactan, acetylated mannose, glucosamine and galactosamine.

Murray teaches that galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine and xylose are the principal sugars found in human glycoproteins. *See* Table 56-4.

The teachings of Murray are set forth above. Murray does not teach a method for the producing correctly structured and functioning glycoproteins and/or glycolipids in a human comprising the administration of a dietary supplement comprising a nutritionally effective amount of least one saccharide in monomeric, oligomeric or polymeric form selected from the recited Markush group. However, it would have been obvious to one of ordinary skill in the art to administer the a dietary supplement comprising any of the sugars taught by Murray to provide the instantly claimed method because at the time the invention was made Murray taught that the claim-designated saccharides were principal the building blocks of glycoproteins found in humans and important in the phenomenon of metastasis, especially metastasis in cancer cells. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to use the instantly claimed saccharides in the making of a dietary supplement comprising a nutritionally effective amount of at least one saccharide for administration to a human to provide the instantly claimed method because Murray teaches that galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine and xylose are the principal sugars found in human glycoproteins,

which have numerous and diverse biological functions, as set forth in Table 56-2. Furthermore, on page 665 to page 666, under "*SUMMARY*" Murray teaches, "The oligosaccharide chains are important to glycoproteins in modulating their solubility and viscosity, in protecting them against proteolysis, in their biologic actions, and in their participation in normal and abnormal cell-cell interactions (eg, sperm-egg interaction, development, and cancer, respectively.)." Thus, the instantly claimed invention is more than the administration of sugars to humans to provide the beneficial functional effect for producing glycoproteins in humans, wherein the administration of the claim-designated sugars were already known in the art to be critical in the production of correctly structured and properly functioning glycoproteins and/or glycolipids in humans and important in vital biological activities of the human body.

From the teachings of Murray, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

Claims 3-8 are rejected under 35 U.S.C. 103(a) as being obvious over Murray et al. (UU1, Robert K. Murray et al., Harper's Biochemistry, Appleton & Lange, 1996, pages 648-649.) in view of Beldman et al. (U) and Remington (V) and Uchida (N).

Applicant's claimed invention of Claim 3-6 was set forth above. Applicant further claims the method of claim 5, wherein the physical digestion is conducted by enzymatic

digestion, acid hydrolysis or base hydrolysis. Applicant further claims the method of claim 4, wherein the biological digestion is conducted with microbes selected from the group consisting of bacteria, fungi and molds.

The obvious teachings of Murray are set forth above. The obvious teachings of Murray teach the instantly claimed invention except for wherein prior to administration, the oligomeric or polymeric forms of the saccharides are predigested into a mixture of mono and oligosaccharides. However, it would have been obvious to one of ordinary skill in the art to modify the obvious teachings of Murray by administrating any of the claim-designated oligomeric or polymeric forms of the instantly claimed saccharides as a predigested mixture of mono and oligosaccharides to provide the instantly claimed method because at the time the invention was made the predigestion of oligomeric or polymeric forms of saccharides by either physical digestion, chemical digestion and biological digestion that are obtained from natural biological materials, such as plant materials, for use in the making of dietary supplements was well known in the art, as evidenced by the teachings of Remington, Beldman and Uchida. For instance, Remington teaches that various forms of saccharides contained therein vegetable food materials, such as cereal, can be made more readily available to the human body by predigestion thereof the food material by physical digestion or enzymatic digestion. In another instance, Beldman teaches hydrolysis of plant derived polysaccharides can be affected by physical treatments comprising hammer milling and heating plant material, enzymatic treatment comprising contacting plant material with enzyme solutions, and chemical treatment of plant material comprising contacting plant material with acidic or

basic solutions. Finally, as set forth above, Uchida teaches predigestion of polymeric or oligomeric forms of saccharides by ultra-sonic treatment and high-shear treatment. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to modify the obvious teachings of Murray by administrating any of the claim-designated oligomeric or polymeric forms of the instantly claimed saccharides as a predigested mixture of mono and oligosaccharides to provide the instantly claimed method because Remington teaches that the predigestion of plant food materials comprising polymeric or oligomeric forms of saccharides and used as dietary supplements by humans provides a suitable predigested food material for people with and delicate digestive systems and requires not further preparation before use, on page 150, Column 1, lines 11-27; Beldman suggests that the choice of pretreating a polymeric or an oligomeric form of a saccharide by either physical, chemical or biological digestion depends on the type(s) of saccharide(s) one desires to obtain and the source of the polymeric or oligomeric form of saccharide; and, Uchida teaches that pretreatment of a polymeric or an oligomeric form of a saccharide provides a more purified, and less viscous product, in Column 4, line 7-21. Thus, the instantly claimed method would have been no more than a matter of judicious selection for one of ordinary skill the art at the time the invention was made to pick and choose any of the instantly claimed treatments for the predigestion of oligomeric or polymeric forms of saccharides, given that Remington, Beldman and Uchida teach that the predigestion of such saccharides by physical digestion, chemical

digestion and biological digestion are conventionally used in the preparation of dietary supplements comprising saccharides intended to be administered to humans.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michele C. Flood.

MICHELE FLOOD
PRIMARY EXAMINER

Michele Flood
Examiner
Art Unit 1654

MCF
April 4, 2005